

DATA EVALUATION REPORT

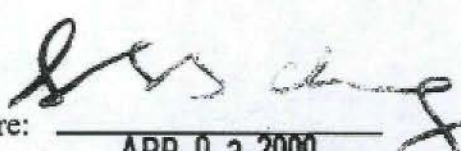
ISOPROPANOL (FOOD CONTACT HARD SURFACE SANITIZER 6609-NS-I-66-B-1)

STUDY TYPE: ACUTE DERMAL TOXICITY - RABBIT [870.1200 (81-2)]
MRID 44977402

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K0190

Primary Reviewer:
Susan Chang, M.S.

Signature: 

Date: APR 03 2000

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: HT Borges

Date: APR 03 2000

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross

Date: APR 03 2000

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L.A. Wilson

Date: APR 03 2000

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

EPA Reviewer: Wallace Powell, Ph.D. _____, Date _____

EPA Work Assignment Manager: Nader Elkassabany, Ph.D. _____, Date _____

Antimicrobials Division (9510C)

DATA EVALUATION RECORD**STUDY TYPE:** Acute Dermal Toxicity - Rabbit [OPPTS 870.1200 (§81-2)]**DP BARCODE:** D261694**SUBMISSION CODE:** S572362**P.C. CODE:** 047501**CASE NO.:** 065184**TEST MATERIAL:** Food Contact Hard Surface Sanitizer 6609-NS-I-66-B-1**SYNONYMS:** Not reported**CITATION:** Kukulinski, M. (1999) Acute dermal toxicity study. Tox Monitor Laboratories, Inc., 33 West Chicago Avenue, Oak Park, IL 60302. Study 99-0166-4, September 13, 1999. MRID 44977402. Unpublished.**SPONSOR:** Nice-Pak Products, 2 Nice-Pak Park, Orangeburg, NY 10962**EXECUTIVE SUMMARY:** In an acute dermal toxicity study (MRID 44977402) approximately 10% of the body surface area of five male and five female young adult New Zealand White rabbits was dermally exposed to 2000 mg/kg Food Contact Hard Surface Sanitizer 6609-NS-I-66-B-1 (Lot No. not reported) for 24 hours. The animals were observed for 14 days.

None of the animals died during the study. One rabbit was normal throughout the study. Erythema and edema were noted on day 1 on 9/10 and 5/10 rabbits, respectively. Erythema persisted on some of the rabbits through day 4. Scaling of the stratum corneum was noted on 6/10 rabbits starting on day 4. By day 10, all rabbits returned to normal. All rabbits had normal body weight gains. No gross changes were observed at necropsy.

The dermal LD₅₀ for males, females, and combined was > 2000 mg/kg (Limit Test).**Food Contact Hard Surface Sanitizer 6609-NS-I-66-B-1 is in TOXICITY CATEGORY III based on the LD₅₀.**

This acute dermal study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for an acute dermal study [870.1200 (81-2)] in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Food Contact Hard Surface Sanitizer 6609-NS-I-66-B-1

Description: clear liquid

Lot/Batch #: not reported

Composition: not reported

2. Vehicle and/or positive control

None

3. Test animals

Species: rabbit

Strain: New Zealand White

Age and/or weight at dosing: young adult; males: 2.03-2.21 kg, females: 2.05-2.74 kg

Source: Kuiper Rabbitry, Gary, IN

Acclimation period: at least 4 days

Diet: Purina Rabbit Chow, *ad libitum*

Water: *ad libitum*

Housing: individually in stainless steel cages

Environmental conditions:

Temperature: not reported

Humidity: not reported

Air changes: not reported

Photoperiod: not reported

B. STUDY DESIGN AND METHODS

1. In life dates

Start: August 11, 1999; end: August 25, 1999

2. Animal assignment and treatment

The study was conducted as a limit test using five male and five female rabbits given a single 2000 mg/kg dose of Food Contact Hard Surface Sanitizer 6609-NS-I-66-B-1 applied to the shaved area on the dorsal trunk (approximately 10% of the body surface). The application site was covered with gauze dressing, a sleeve of plastic sheeting, and secured with non-irritating tape. The covering was removed 24 hours later and the site wiped for any residual test material. The animals were observed for clinical signs of toxicity frequently on the day of test and at least daily thereafter for

14 days. They were weighed prior to test material application, and on study days 7 and 14. All rabbits were sacrificed and necropsied.

3. Statistics

Calculation of the dermal LD₅₀ was not required.

II. RESULTS AND DISCUSSION

A. MORTALITY

None of the rabbits died during the study.

The dermal LD₅₀ for males, females, and combined was > 2000 mg/kg. This places Food Contact Hard Surface Sanitizer 6609-NS-I-66-B-1 in TOXICITY CATEGORY III.

B. CLINICAL OBSERVATIONS

One rabbit was normal throughout the study. Erythema and edema were noted on day 1 on 9/10 and 5/10 rabbits, respectively. Erythema persisted on some of the rabbits through day 4. Scaling of the stratum corneum was noted on 6/10 rabbits starting on day 4 or 5. By day 10, all rabbits returned to normal.

C. BODY WEIGHT

All rabbits had normal body weight gains.

D. NECROPSY

No gross changes were observed.

E. DEFICIENCIES

The lot no. of the test material and environmental conditions of the animal room were not reported. These would not affect the study results.